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**DEPARTMENT OF JUSTICE
Drug Enforcement Administration**

**[Docket No. 17-37]
Kenneth N. Woliner, M.D.
Decision and Order**

On June 6, 2017, the Assistant Administrator, Diversion Control Division, Drug Enforcement Administration (DEA), issued an Order to Show Cause to Kenneth N. Woliner, M.D. (Respondent), of Boca Raton, Florida. The Show Cause Order proposed the revocation of Respondent's DEA Certificate of Registration No. BW6830500 on the ground that he "do[es] not have authority to handle controlled substances in the State of Florida, the [S]tate in which [he is] registered with the DEA." Order to Show Cause, at 1 (citing 21 U.S.C. §§ 823(f) and 824(a)(3)).

With respect to the Agency's jurisdiction, the Show Cause Order alleged that Respondent is the holder of Certificate of Registration No. BW6830500, pursuant to which he is authorized to dispense controlled substances as a practitioner in schedules II through V, at the registered address of 9325 Glades Road, Suite 104, Boca Raton, Florida. *Id.* The Order also alleged that this registration does not expire until May 31, 2018. *Id.*

Regarding the substantive grounds for the proceeding, the Show Cause Order alleged that on December 29, 2016, the Florida Board of Medicine "revoked [his] authority to practice medicine," and he is therefore "without authority to handle controlled substances in Florida, the [S]tate in which [he is] registered with the DEA." *Id.* Based on his "lack of authority to [dispense] controlled substances in . . . Florida," the Order asserted that "DEA must revoke" his registration. *Id.* (citing 21 U.S.C. 823(f)(1) and 824(a)(3)).

The Show Cause Order notified Respondent of (1) his right to request a hearing on the allegations or to submit a written statement in lieu of a hearing, (2) the procedure for electing

either option, and (3) the consequence for failing to elect either option. *Id.* at 2 (citing 21 CFR 1301.43). The Show Cause Order also notified Respondent of his right to submit a corrective action plan (hereinafter, CAP) to the Assistant Administrator, Diversion Control Division, and the procedure for doing so. *Id.* at 2-3.

On July 6, 2017, Respondent filed a letter with the Office of Administrative Law Judges pursuant to which he requested a hearing on the allegations of the Show Cause Order. Letter from Respondent to Hearing Clerk (dated July 3, 2017) (hereinafter, Hearing Request). In his letter, Respondent did not dispute that his Florida medical license “was revoked.” *Id.* at 1. He maintained, however, that his license “was revoked for issues not relating to controlled substances; and that the revocation . . . is currently under appeal at Florida’s District Court of Appeal.” *Id.* Respondent also advised that he “has not been convicted of any crime, much less one involving controlled substances.” *Id.* Also on July 6, 2017, Respondent submitted his CAP by letter to the Assistant Administrator, Diversion Control Division. Letter from Respondent to Assistant Administrator Louis J. Milione (dated July 3, 2017). In his CAP, Respondent explained:

My corrective action plan is to have my case overturned on appeal. The Initial Brief on the Merits was filed on 6/7/2017. Barring the Court granting extensions of time (if filed), the Department of Health is was [sic] required to file their Answer Brief by 6/27/2017, and our Reply is due 20 days after service of the Answer Brief.

It would seem prudent for the DEA to “postpone the proceedings” until the 1st District Court of Appeal rules on this matter.

Id. at 1.

Upon receipt of Respondent’s Hearing Request and CAP, the matter was placed on the docket of the Office of Administrative Law Judges and assigned to Chief Administrative Law Judge John J. Mulrooney, II (hereinafter, CALJ). On July 6, 2017, the CALJ issued an order

noting that Respondent was appearing *pro se* and advised him “that he has the right to seek representation by a qualified attorney at his own expense.” Order Directing the Filing of Government Evidence of Lack of State Authority Allegation and Briefing Schedule, at 1 & n.1 (citing 21 CFR § 1316.50). The CALJ also ordered the Government to file evidence to support the allegation that Respondent lacks state authority to handle controlled substances and an accompanying motion for summary disposition no later than July 18, 2017. *Id.* The CALJ further directed Respondent to file his response to any summary disposition motion no later than August 1, 2017. *Id.* at 2.

On July 6, 2017, the Acting Assistant Administrator received Respondent’s CAP letter. *See* Letter from Acting Assistant Administrator Demetra Ashley to Respondent (dated July 11, 2017) (hereinafter CAP Rejection Ltr), at 1. However, on July 10, 2017, before the Acting Assistant Administrator had ruled on Respondent’s CAP (and eight days before its summary disposition motion was due), the Government filed its Motion for Summary Disposition. In its Motion, the Government argued that it is undisputed that the Florida Board of Medicine revoked Respondent’s Florida medical license. Government’s Motion for Summary Disposition (Govt. Mot.), at 2. The Government further argued “that the possession of authority to dispense controlled substances under the laws of the State in which a practitioner engages in professional practice is a fundamental condition for both obtaining and maintaining a practitioner’s registration” under the Controlled Substances Act (CSA). *Id.* at 3 (citation omitted). As support for its summary disposition request, the Government attached, *inter alia*, a certified copy of the Florida Board of Medicine’s December 29, 2016 “Final Order” revoking Respondent’s license to

practice medicine in the State of Florida. *See* Govt. Mot., Appendix (Appx.) B, at 13.¹ On July 11, 2017, the Acting Assistant Administrator rejected Respondent's CAP and further "determined there is no potential modification of your []CAP that could or would alter my decision in this regard." CAP Rejection Ltr, at 1.

On August 1, 2017, Respondent filed a responsive pleading that opposed the Government's Motion and requested a stay in the proceedings. Respondent's Opposition to Government's Motion for Summary Disposition (hereinafter, Resp. Opp. or Opposition). Although Respondent did not dispute that his medical license had been revoked by Florida's Board of Medicine, he contended that this fact does not categorically support the revocation of his registration. *Id.* at 6 (citing *Joe W. Morgan, D.O.*, 78 FR 61961 (2013)). He also argued that revoking his registration without an administrative hearing violates his rights under the Fifth Amendment's Due Process Clause. *Id.* He further argued that "the Government has not shown that Respondent's DEA registration is inconsistent with the public interest by any factor in § 824(a)(4) because, *inter alia*, (1) the "State of Florida has not made a recommendation regarding Respondent's ability to prescribe controlled substances," (2) Respondent has not been charged or convicted of a federal or state crime related to controlled substances, and (3) that "[t]he disciplinary event in question did not relate to controlled substances in any fashion." *Id.* at 9. Finally, Respondent argued that the Agency should delay any decision to revoke his registration because the Government would not be prejudiced and he believes that he "is very much likely to prevail in his appeal" before Florida's 1st District Court of Appeal, which he

¹ The Government also attached a Declaration from a Diversion Investigator assigned to DEA's West Palm Beach Office stating that the Florida Board's Order attached to the Government's motion for summary decision "is a certified copy of the documents I obtained from the Florida Board of Medicine." Govt. Mot., Appx. C, at 1.

“expected” would decide the merits of his appeal “no later than September 19, 2017.” *Id.* at 10-12.

The CALJ rejected Respondent’s request for a stay, noting that “revocation is warranted even where a practitioner’s state authority has been summarily suspended and the State has yet to provide the practitioner with a hearing to challenge the State’s action and at which he . . . may ultimately prevail.” Order Denying the Respondent’s Request for Stay, Granting the Government’s Motion for Summary Disposition, and Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge (R.D.), at 4 (internal quotations and citations omitted)). The CALJ also concluded that Respondent had no constitutional right to a hearing before the Agency because he “was apparently afforded a full hearing, where he was represented by counsel, before the [Florida] Board revoked his medical license.” *Id.* at 4 & n.3. The CALJ noted that DEA has previously held “that a stay in administrative enforcement proceedings is ‘unlikely to ever be justified’ due to ancillary proceedings involving the Respondent.” *Id.* at 4 (quoting *Grider Drug #1 & Grider Drug #2*, 77 FR 44070, 44104 n.97 (2012)).² The CALJ also rejected Respondent’s claim that the loss of his Florida medical license categorically supports the revocation of his DEA registration and found Respondent’s reliance on the *Joe W. Morgan, D.O.* case and others to be misplaced. *Id.* at 6 n.9.

The CALJ then found summary disposition appropriate in this case because “no dispute exists over the fact that the Respondent currently lacks state authority to handle controlled substances in Florida due to the Board[’s] Order dated December 29, 2017, which revoked his

² I agree with this statement of the Agency’s precedents. However, the CALJ also cited *Odette L. Campbell*, 80 FR 41062 (2015), as contrary authority. *See id.* The CALJ characterized *Campbell* as “holding revocation proceedings in abeyance at the post-hearing adjudication level for a lengthy period pending the resolution of both criminal fraud charges and concurrent state administrative proceedings against the respondent,” *id.*, even though I have repeatedly issued final decisions rejecting this reading of *Campbell*. *See e.g., Judson H. Somerville*, 82 FR 21408, 21409 n.3 (2017). For the same reasons set forth in those cases, including the fact that *Campbell* involved an application and not a revocation at the time the proceeding was held in abeyance, I again reject the CALJ’s reading of *Campbell*.

state license to practice medicine.” *Id.* at 7. Reasoning that “[b]ecause . . . Respondent lacks state authority at the present time . . . he is not entitled to maintain his DEA registration,” the CALJ granted the Government’s request for summary disposition and recommended that I revoke Respondent’s registration and deny any pending applications. *Id.*

Neither party filed exceptions to the CALJ’s Recommended Decision.³ Thereafter, the record was forwarded to my Office for Final Agency Action. Having reviewed the record, I adopt the CALJ’s factual finding that Respondent’s medical license has been revoked and his ultimate conclusion that Respondent does not hold authority under Florida law to handle controlled substances, the State in which he holds his registration with the Agency, and is thus not entitled to maintain his registration. I also adopt the CALJ’s ruling rejecting Respondent’s request for a stay of this proceeding. I further adopt the CALJ’s recommendation that I revoke his registration and deny any pending application. I make the following factual findings.

FINDINGS OF FACT

Respondent is a holder of DEA Certificate of Registration No. BW6830500, pursuant to which he is authorized to dispense controlled substances in schedules II through V as a practitioner, at the address of Holistic Family Medicine, LLC, 9325 Glades Road, Suite 104, Boca Raton, Florida. Govt. Mot., Appx. A. This registration does not expire until May 31, 2018. *Id.*

On December 29, 2016, the Florida Board of Medicine issued a final order revoking Respondent’s license to practice medicine in the State of Florida. Govt. Mot., Appx. B, at 13. The Florida Board adopted the recommended order of the state administrative law judge who

³ Although Respondent reached out to the CALJ’s law clerk to determine the “process for filing ‘exceptions,’” and the law clerk advised Respondent of that process and directed Respondent to 21 CFR 1316.66, the administrative record does not include any exceptions filed by Respondent. Aug. 8, 2008 Email from Law Clerk to Respondent, at 1. Government counsel was carbon copied on the entire email exchange. *See id.*

conducted a hearing at which Respondent was present and represented by counsel. *Id.* at 1. The Board considered the Recommended Order, Exceptions to the Recommended Order and Response to Exceptions, and adopted the conclusions of law set forth in the Recommended Order,⁴ and ordered that Respondent's Florida license to practice medicine be revoked as of December 29, 2016. *Id.* at 13.

On August 28, 2017, the 1st District Court of Appeals of Florida affirmed the decision and final order of the Florida Department of Health revoking Respondent's license to practice medicine, and denied rehearing on October 9, 2017. *Kenneth Woliner, M.D. v Department of Health*, No. 1D17-682, slip op. at 1(Fla. Dist. Ct. App. 1st District Aug. 28, 2017), and *reh'g denied* 2017 WL 3696794 (October 9, 2017). I take official notice of this unpublished decision⁵ and find that Respondent does not possess authority to practice medicine in the State of Florida, the State in which he is registered.

DISCUSSION

Pursuant to 21 U.S.C. § 824(a)(3), the Attorney General is authorized to suspend or revoke a registration issued under section 823 of the CSA, "upon a finding that the registrant . . . has had his State license . . . suspended [or] revoked . . . by competent State authority and is no longer authorized by State law to engage in the . . . dispensing of controlled substances." Also, DEA has long held that the possession of authority to dispense controlled substances under the

⁴ The Recommended Order of the Florida Administrative Law Judge was not included in the Government's evidence.

⁵ Under the Administrative Procedure Act (APA), an agency "may take official notice of facts at any stage in a proceeding – even in the final decision." U.S. Dept. of Justice, *Attorney General's Manual on the Administrative Procedure Act* 80 (1947) (Wm. W. Gaunt & Sons, Inc., Reprint 1979). In accordance with the APA and DEA's regulations, Respondent is "entitled on timely request to an opportunity to show to the contrary." 5 U.S.C. § 556(e); *see also* 21 CFR 1316.59(e). To allow Respondent the opportunity to refute the facts of which I take official notice, Respondent may file a motion for reconsideration within 15 calendar days of service of this order which shall commence on the date this order is mailed.

laws of the State in which a practitioner engages in professional practice is a fundamental condition for obtaining and maintaining a practitioner's registration. *See, e.g., James L. Hooper*, 76 FR 71371 (2011), *pet. for rev. denied*, 481 Fed. Appx. 826 (4th Cir. 2012); *see also Frederick Marsh Blanton*, 43 FR 27616 (1978) ("State authorization to dispense or otherwise handle controlled substances is a prerequisite to the issuance and maintenance of a Federal controlled substances registration.").

This rule derives from the text of two provisions of the CSA. First, Congress defined "the term 'practitioner' [to] mean[] a . . . physician . . . or other person licensed, registered or otherwise permitted, by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice." 21 U.S.C. § 802(21). Second, in setting the requirements for obtaining a practitioner's registration, Congress directed that "[t]he Attorney General shall register practitioners . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices." 21 U.S.C. § 823(f).

Here, the dispositive question is whether Respondent is currently authorized to dispense controlled substances in Florida, the State in which he is registered. It is undisputed that Florida's Board of Medicine revoked Respondent's license to practice medicine. In his recommendation, the CALJ also stated that "no dispute exists over the fact that the Respondent currently lacks state authority to handle controlled substances in Florida due to the Board['s] Order . . . which revoked his state license to practice medicine." R.D., at 7.

Respondent, however, argues in his Opposition that "[t]he State of Florida has not made a recommendation regarding Respondent's ability to prescribe controlled substances" – casting doubt on the CALJ's statement that it is undisputed that Respondent lacks this ability. Resp.

Opp. at 9. Thus, the question of whether Respondent is currently authorized to dispense controlled substances in Florida is in dispute.

This question is not a question of fact but of law. If this question were purely a fact question, as the CALJ suggests, then summary disposition in this case would have been inappropriate. However, I find that this dispositive question is a disputed legal question, not a question of fact. Specifically, under Florida law, a “[p]ractitioner” includes “a physician licensed under chapter 458” of the Florida statutes, and a “[p]hysician” under chapter 458 “means a person who is licensed to practice medicine in” Florida. Fla. Stat. §§ 893.02(23), 458.305(4). Florida law also states that the “[p]ractice of medicine,” in turn, “means the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition.” *Id.* § 458.305(3). Thus, I find that Florida law prohibits Respondent from dispensing controlled substances within the meaning of the CSA because, when the Florida Board of Medicine revoked his license to practice medicine on December 29, 2016, it had the legal effect of also taking away Respondent’s authority to issue any prescriptions for any “physical or mental condition.” *See Christina B. Paylan, M.D.*, 80 FR 69979, 69979 (2015) (holding that Respondent “lacks authority under Florida law to dispense controlled substances within the meaning of the CSA” because “Respondent’s license ‘to practice as a medical doctor’” had been suspended) (citing Fla. Stat. §§ 458.305(3), (4)); *Reams v. State*, 279 So. 2d 839, 842 (Fla. 1973) (holding that prescribing “vitamins or food” rather than “medicines” without a medical license constitutes an unlicensed practice of medicine under Florida law).

Accordingly, as a matter of law, Respondent lacked the authority to handle controlled substances in Florida beginning on December 29, 2016 (when the Florida Board of Medicine

revoked his State medical license), and he is therefore not entitled to maintain his DEA registration.

Moreover, because “the controlling question” in a proceeding brought under 21 U.S.C. § 824(a)(3) is whether the holder of a DEA registration “is currently authorized to handle controlled substances in the [S]tate,” *Hooper*, 76 FR at 71371 (quoting *Anne Lazar Thorn*, 62 FR 12847, 12848 (1997)), the Agency has also long held that revocation is warranted even where a practitioner has lost his state authority by virtue of the State’s use of summary process and the State has yet to provide a hearing to challenge the suspension. *Bourne Pharmacy*, 72 FR 18273, 18274 (2007); *Wingfield Drugs*, 52 FR 27070, 27071 (1987). For the same reasons, given that the Florida Board of Medicine had revoked Respondent’s state license, it is of no consequence that Respondent could have prevailed on his appeal to the 1st District Court of Appeals of Florida.⁶ In any event, and as already noted, that court has since affirmed the revocation of Respondent’s medical license.

As for Respondent’s CAP, I conclude that there were adequate grounds for denying it. Specifically, Respondent’s position in his CAP is identical to his principal argument seeking a stay of summary disposition of the Show Cause Order that I have already rejected; namely, that his DEA registration should not be revoked until the conclusion of his appeal to Florida’s 1st District Court of Appeal. Thus, I agree with the Agency’s denial of Respondent’s CAP for the same reasons I set forth above for denying Respondent’s identical argument to stay summary

⁶ Similarly, and contrary to Respondent’s claim, Due Process did not require the CALJ to delay summary disposition of the case until his appeal to the First District Court of Appeals of Florida had been decided. Resp. Opp. at 10-12. Rather, Due Process required the CALJ to provide Respondent the opportunity to respond to the Order to Show Cause and the Government’s Motion for Summary Disposition. The CALJ did provide Respondent such an opportunity, and the Respondent did so respond.

I also agree with the CALJ’s recommendation (R.D. at 6 n.9) that I reject, and I do reject, Respondent’s argument that revocation is not required in this case based on the *Joe W. Morgan* case and the other Agency precedent cited by Respondent.

disposition. In addition, like his stay argument, the need to address the adequacy of Respondent's CAP is now moot because his appeal was denied.

I will therefore reject Respondent's CAP and adopt the CALJ's recommendation that I revoke Respondent's registration and deny any pending applications to renew or modify his registration. *See* R.D. at 7.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. §§ 823(f) and 824(a), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration No. BW6830500, issued to Kenneth N. Woliner, M.D., be, and it hereby is, revoked. I further order that any pending application of Kenneth N. Woliner to renew or modify the above registration, or any pending application of Kenneth N. Woliner for any other registration, be, and it hereby is, denied. This Order is effective immediately.⁷

Dated: February 7, 2018.

Robert W. Patterson,
Acting Administrator.

⁷ For the same reasons which led the Florida Board of Medicine to revoke Respondent's medical license, I conclude that the public interest necessitates that this Order be effective immediately. 21 CFR 1316.67.

